

exceed 0.07 percent of the weight of the capsule.

(2) As a moisture barrier on powders of ascorbic acid or its salts in an amount not to exceed 7 percent of the weight of the powder.

[42 FR 14491, Mar. 15, 1977, as amended at 49 FR 10104, Mar. 19, 1984]

### Subpart D—Special Dietary and Nutritional Additives

#### § 172.310 Aluminum nicotinate.

Aluminum nicotinate may be safely used as a source of niacin in foods for special dietary use. A statement of the concentration of the additive, expressed as niacin, shall appear on the label of the food additive container or on that of any intermediate premix prepared therefrom.

#### § 172.315 Nicotinamide-ascorbic acid complex.

Nicotinamide-ascorbic acid complex may be safely used in accordance with the following prescribed conditions:

(a) The additive is the product of the controlled reaction between ascorbic acid and nicotinamide, melting in the range 141°C to 145°C.

(b) It is used as a source of ascorbic acid and nicotinamide in multivitamin preparations.

#### § 172.320 Amino acids.

The food additive amino acids may be safely used as nutrients added to foods in accordance with the following conditions:

(a) The food additive consists of one or more of the following individual amino acids in the free, hydrated or anhydrous form or as the hydrochloride, sodium or potassium salts:

L-Alanine  
L-Arginine  
L-Asparagine  
L-Aspartic acid  
L-Cysteine  
L-Cystine  
L-Glutamic acid  
L-Glutamine  
Aminoacetic acid (glycine)  
L-Histidine  
L-Isoleucine  
L-Leucine  
L-Lysine  
DL-Methionine (not for infant foods)  
L-Methionine

L-Phenylalanine  
L-Proline  
L-Serine  
L-Threonine  
L-Tryptophan  
L-Tyrosine  
L-Valine

(b) The food additive meets the following specifications:

(1) As found in "Food Chemicals Codex," National Academy of Sciences/National Research Council (NAS/NRC), 3d Ed. (1981), which is incorporated by reference (copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408) for the following:

L-Alanine  
L-Arginine  
L-Arginine Monohydrochloride  
L-Cysteine Monohydrochloride  
L-Cystine  
Aminoacetic acid (glycine)  
L-Leucine  
DL-Methionine  
L-Methionine  
L-Tryptophan  
L-Phenylalanine  
L-Proline  
L-Serine  
L-Threonine  
Glutamic Acid Hydrochloride  
L-Isoleucine  
L-Lysine Monohydrochloride  
Monopotassium L-glutamate  
L-Tyrosine  
L-Valine

(2) As found in "Specifications and Criteria for Biochemical Compounds," NAS/NRC Publication, 3rd Ed. (1972), which is incorporated by reference (copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408) for the following:

L-Asparagine  
L-Aspartic acid  
L-Glutamine  
L-Histidine

(c) The additive(s) is used or intended for use to significantly improve the biological quality of the total protein in

a food containing naturally occurring primarily-intact protein that is considered a significant dietary protein source, provided that:

(1) A reasonable daily adult intake of the finished food furnishes at least 6.5 grams of naturally occurring primarily intact protein (based upon 10 percent of the daily allowance for the "reference" adult male recommended by the National Academy of Sciences in "Recommended Dietary Allowances," NAS Publication No. 1694, 7th Ed. (1968), which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(2) The additive(s) results in a protein efficiency ratio (PER) of protein in the finished ready-to-eat food equivalent to casein as determined by the method specified in paragraph (d) of this section.

(3) Each amino acid (or combination of the minimum number necessary to achieve a statistically significant increase) added results in a statistically significant increase in the PER as determined by the method described in paragraph (d) of this section. The minimum amount of the amino acid(s) to achieve the desired effect must be used and the increase in PER over the primarily-intact naturally occurring protein in the food must be substantiated as a statistically significant difference with at least a probability (P) value of less than 0.05.

(4) The amount of the additive added for nutritive purposes plus the amount naturally present in free and combined (as protein) form does not exceed the following levels of amino acids expressed as percent by weight of the total protein of the finished food:

	Percent by weight of total protein (expressed as free amino acid)
L-Alanine .....	6.1
L-Arginine .....	6.6
L-Aspartic acid (including L-asparagine) .....	7.0
L-Cystine (including L-cysteine) .....	2.3

	Percent by weight of total protein (expressed as free amino acid)
L-Glutamic acid (including L-glutamine) .....	12.4
Aminoacetic acid (glycine) .....	3.5
L-Histidine .....	2.4
L-Isoleucine .....	6.6
L-Leucine .....	8.8
L-Lysine .....	6.4
L- and DL-Methionine .....	3.1
L-Phenylalanine .....	5.8
L-Proline .....	4.2
L-Serine .....	8.4
L-Threonine .....	5.0
L-Tryptophan .....	1.6
L-Tyrosine .....	4.3
L-Valine .....	7.4

(d) Compliance with the limitations concerning PER under paragraph (c) of this section shall be determined by the method described in sections 43.212–43.216, "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877–2504, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408. Each manufacturer or person employing the additive(s) under the provisions of this section shall keep and maintain throughout the period of his use of the additive(s) and for a minimum of 3 years thereafter, records of the tests required by this paragraph and other records required to assure effectiveness and compliance with this regulation and shall make such records available upon request at all reasonable hours by any officer or employee of the Food and Drug Administration, or any other officer or employee acting on behalf of the Secretary of Health and Human Services and shall permit such officer or employee to conduct such inventories of raw and finished materials on hand as he deems necessary and otherwise to check the correctness of such records.

(e) To assure safe use of the additive, the label and labeling of the additive and any premix thereof shall bear, in addition to the other information required by the Act, the following:

(1) The name of the amino acid(s) contained therein including the specific optical and chemical form.

(2) The amounts of each amino acid contained in any mixture.

(3) Adequate directions for use to provide a finished food meeting the limitations prescribed by paragraph (c) of this section.

(f) The food additive amino acids added as nutrients to special dietary foods that are intended for use solely under medical supervision to meet nutritional requirements in specific medical conditions and comply with the requirements of part 105 of this chapter are exempt from the limitations in paragraphs (c) and (d) of this section and may be used in such foods at levels not to exceed good manufacturing practices.

[42 FR 14491, Mar. 15, 1977; 42 FR 56728, Oct. 28, 1977, as amended at 47 FR 11836, Mar. 19, 1982; 49 FR 10104, Mar. 19, 1984; 54 FR 24897, June 12, 1989; 59 FR 14550, Mar. 29, 1994; 61 FR 14480, Apr. 2, 1996]

#### § 172.325 Bakers yeast protein.

Bakers yeast protein may be safely used in food in accordance with the following conditions:

(a) Bakers yeast protein is the insoluble proteinaceous material remaining after the mechanical rupture of yeast cells of *Saccharomyces cerevisiae* and removal of whole cell walls by centrifugation and separation of soluble cellular materials.

(b) The additive meets the following specifications on a dry weight basis:

(1) Zinc salts less than 500 parts per million (ppm) as zinc.

(2) Nucleic acid less than 2 percent.

(3) Less than 0.3 ppm arsenic, 0.1 ppm cadmium, 0.4 ppm lead, 0.05 ppm mercury, and 0.3 ppm selenium.

(c) The viable microbial content of the finished ingredient is:

(1) Less than 10,000 organisms/gram by aerobic plate count.

(2) Less than 10 yeasts and molds/gram.

(3) Negative for *Salmonella*, *E. coli*, coagulase positive *Staphylococci*, *Clostridium perfringens*, *Clostridium botulinum*, or any other recognized microbial pathogen or any harmful microbial toxin.

(d) The ingredient is used in food as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

#### § 172.330 Calcium pantothenate, calcium chloride double salt.

The food additive calcium chloride double salt of calcium pantothenate may be safely used in foods for special dietary uses in accordance with good manufacturing practice and under the following prescribed conditions:

(a) The food additive is of the *d* (dextrorotatory) or the *dl* (racemic) form.

(b) To assure safe use of the additive, the label and labeling of the food additive container, or that of any intermediate premixes prepared therefrom, shall bear, in addition to the other information required by the Act, the following:

(1) The name of the additive "calcium chloride double salt of *d*-calcium pantothenate" or "calcium chloride double salt of *dl*-calcium pantothenate", whichever is appropriate.

(2) A statement of the appropriate concentration of the additive, expressed as pantothenic acid.

#### § 172.335 D-Pantothenamide.

The food additive D-pantothenamide as a source of pantothenic acid activity, may be safely used in foods for special dietary use in an amount not in excess of that reasonably required to produce its intended effect.

#### § 172.340 Fish protein isolate.

(a) The food additive fish protein isolate may be safely used as a food supplement in accordance with the following prescribed conditions:

(1) The additive shall consist principally of dried fish protein prepared from the edible portions of fish after removal of the heads, fins, tails, bones, scales, viscera, and intestinal contents.

(2) The additive shall be derived only from species of bony fish that are generally recognized by qualified scientists as safe for human consumption and that can be processed as prescribed to meet the required specifications.

(3) Only wholesome fresh fish otherwise suitable for human consumption may be used. The fish shall be handled expeditiously under sanitary